UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA AB, ASTRAZENECA LP, KBI-E INC., and POZEN INC., Plaintiffs, v. DR. REDDY'S LABORATORIES INC. and DR. REDDY'S LABORATORIES LTD., Defendants.	CIVIL ACTION NO. 11-cv-02317-JAP-DEA (Consolidated for discovery purposes with Civil Action No. 11-cv-04275-JAP-DEA)
ASTRAZENECA AB, ASTRAZENECA LP, KBI-E INC., and POZEN INC., Plaintiffs, v. LUPIN LTD. and LUPIN PHARMACEUTICALS INC., Defendants.	CIVIL ACTION NO. 11-cv-04275-JAP-DEA

PLAINTIFFS' OPENING *MARKMAN* SUBMISSION

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I. BACKGROUND

A. Overview

Plaintiffs AstraZeneca AB; AstraZeneca LP; KBI-E Inc. (collectively, "AstraZeneca"); and Pozen Inc. ("Pozen") respectfully submit their Opening *Markman* Submission. This is a Hatch–Waxman patent infringement action. AstraZeneca asserts that Defendants Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd. ("Dr. Reddy's"); and Defendants Lupin Ltd. and Lupin Pharmaceuticals Inc. ("Lupin") infringe six patents related to AstraZeneca's drug product Vimovo®. The cases against Dr. Reddy's and Lupin (collectively, "Defendants") have been consolidated for purposes of discovery, and Defendants have proposed one set of claim constructions. The patents-in-suit are U.S. Patent Nos. 6,926,907; 6,875,872; 5,714,504; 6,369,085; 7,411,070; and 7,745,466.

AstraZeneca holds approved New Drug Application No. 022511 for Vimovo®. Vimovo® is a combination drug product, which contains the active ingredients naproxen (a non-steroidal anti-inflammatory drug, or "NSAID") and esomeprazole magnesium trihydrate (a proton-pump inhibitor, or "PPI"). Vimovo® is indicated to relieve the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis, while decreasing the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers. The esomeprazole magnesium trihydrate in Vimovo® is the same active ingredient as in AstraZeneca's Nexium® (used to treat gastrointestinal disorders).

B. Vimovo®

When combined in Vimovo®, naproxen acts as a pain reliever and inflammation reducer, while esomeprazole magnesium decreases the risk of developing stomach ulcers, a common side effect of long-term, daily NSAID use. Vimovo's® effectiveness not only results from the

combination of naproxen and esomeprazole magnesium in a single tablet, but also from the particular way the two drugs are released from the tablet in the body.

Sufferers of chronic pain often take daily doses of NSAIDs for pain relief. But NSAIDs tend to weaken the mucosal lining of the stomach, and with long-term, daily use, that damage can lead to the development of stomach ulcers. Because PPIs can reduce the amount of acid in the stomach, many researchers believed that PPIs could reduce the occurrence of stomach ulcers in patients taking long-term, daily doses of NSAIDs. As a result, there were efforts to combine NSAIDs with PPIs, but those efforts failed to develop an effective combination product. Then, in the early 2000s, Dr. John Plachetka, the founder of Pozen, invented a better way to combine NSAIDs, like naproxen, with acid inhibitors, like esomeprazole magnesium. Dr. Plachetka's invention ensures the coordinated delivery of the two drugs and reduces the side effects previously associated with long-term, daily use of NSAIDs alone.

Prior to Dr. Plachetka's invention, it was widely believed that PPIs ***required*** an enteric coating to delay the release of the PPI until after it had passed through the stomach; otherwise, the PPI, which is acid-labile, would be destroyed by the acid in the stomach. But, among other things, the delayed release of enteric coated PPI precluded the coordinated delivery of combined dosages of PPI and NSAID, potentially exposing the stomach to NSAIDs before the onset of PPI activity.

Despite the industry-wide belief that PPIs must be enteric coated, Dr. Plachetka's tablet contained an NSAID core surrounded by an outer layer of PPI that was not enteric coated. Without an enteric coating, the PPI would be immediately released from the tablet into the stomach. Dr. Plachetka also included a pH-sensitive coating between the NSAID core and the outer PPI layer. The pH-sensitive coating would prevent release of the NSAID until the amount

of acid in the stomach had been reduced to safe levels by the PPI. Dr. Plachetka believed the combination of the immediate-release PPI and the pH-controlled release NSAID would reduce the occurrence of stomach ulcers associated with the long-term use of NSAIDs.

Pozen undertook clinical studies to prove that Dr. Plachetka's invention safely and effectively reduces the occurrence of stomach ulcers associated with NSAIDs, which led to a partnership with AstraZeneca in 2006 to commercialize Vimovo®.

II. LEGAL PRINCIPLES OF CLAIM CONSTRUCTION

Claim construction is a matter of law for the court. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1455–56 (Fed. Cir. 1998); *see also Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). Claim construction focuses on what a person of ordinary skill in the art would have understood a given claim term to mean at the time of the invention. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). The terms of a claim are generally given their ordinary and customary meaning in the art as of the filing date. *See id.* at 1313–14.

In construing claims, a court first looks to the "intrinsic evidence"—the words of the claims themselves, the specification, and the prosecution history. *Phillips*, 415 F.3d at 1313–17. "[T]he claims themselves provide substantial guidance as to the meaning of particular claim terms," *Phillips*, 415 F.3d at 1314; a construction that stays true to the claim language is the correct construction, *Renishaw PLC v. Marposs Societa Per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998).

The specification and prosecution history provide further guidance for construing claims. *See Phillips*, 415 F.3d at 1315. The specification is "always highly relevant to the claim construction analysis" and is "the single best guide to the meaning of a disputed term." *Id.* (internal quotation marks and citation omitted). Additionally, the prosecution history "can often inform the meaning of the claim language." *Phillips*, 415 F.3d at 1317.

Although the intrinsic evidence is more significant, extrinsic evidence may also be useful in construing claims. Extrinsic evidence includes dictionaries, treatises, and testimony of an inventor or expert witness. *Phillips*, 415 F.3d at 1318. Extrinsic evidence in the form of expert testimony may be useful "for a variety of purposes, such as to provide background on the technology at issue, to explain how an invention works, to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id*. at 1318. However, expert testimony that is conclusory, or clearly at odds with the intrinsic evidence, should be discounted. *See id.* at 1318.

III. CONSTRUCTION OF DISPUTED CLAIM LANGUAGE

Two of the patents-in-suit (the '504 and '872 patents) were the subject of a previous litigation in this Court. In that case (*AstraZeneca AB v. Dr. Reddy's Labs., Ltd.*, Civ. Action No. 05-5553 (D.N.J.) (Pisano, J.)), AstraZeneca sued Dr. Reddy's for infringement of patents covering the Nexium® product, and this Court construed each term of the '504 and '872 patent claims disputed in this litigation. *See AstraZeneca AB v. Dr. Reddy's Labs., Ltd.*, Civ. Action No. 05-5553, 2010 WL 1981790 (D.N.J. May 18, 2010) (Pisano, J.) (Dkt. No. 246). AstraZeneca seeks the same constructions previously adopted by this Court. Dr. Reddy's proposed constructions for the '504 and '872 patent terms are the same as those rejected by this Court.

Each disputed term is addressed in turn below. AstraZeneca's proposed constructions are consistent with the intrinsic and extrinsic evidence. Defendants' constructions are not.

A. '907 Patent Claim Language in Dispute

The '907 patent relates to a pharmaceutical composition combining an acid inhibitor, such as the proton pump inhibitor ("PPI") described and claimed in the other patents-in-suit, with

a non-steroidal anti-inflammatory drug ("NSAID"). The asserted claims[1] require the coordinated release of the two active ingredients: while the acid inhibitor is immediately released regardless of the pH of the surrounding medium, the NSAID is not released unless the pH of the surrounding medium has reached a particular level. Through the coordinated release of the two active ingredients, the NSAID's deleterious effects can be avoided. *See* Declaration of Erica N. Andersen, Ex. 1, Abstract; col.3 ll.63–col.4 ll.2.[2]

The parties dispute the construction of three terms in the asserted claims of the '907 patent. All are found in claim 1.[3] Claim 1, with the disputed terms bolded and/or italicized, reads:

> 1. A pharmaceutical composition in unit dosage form suitable for oral administration to a patient, comprising:
>
> (a) an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon the administration of one or more of said unit dosage forms;
>
> (b) a non-steroidal anti-inflammatory drug (NSAID) in an amount effective to reduce or eliminate pain or inflammation in said patient upon administration of one or more of said unit dosage forms;
>
> and wherein said unit dosage form provides for coordinated release such that:
>
> i) said NSAID is surrounded by **a coating that, upon ingestion of said unit dosage form by said patient, prevents the release of essentially any NSAID from said dosage form unless the pH of the surrounding medium is 3.5 or higher**
>
> ii) **at least a portion of said acid inhibitor is not surrounded by an *enteric coating* and, upon ingestion of said unit dosage form by said patient, is released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5**.

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[1] Plaintiffs are asserting claims 5, 15, 52, 53, and 54.

[2] Unless otherwise specified, all Exhibits are attached to the Declaration of Erica N. Andersen ("Andersen Decl."), accompanying this brief.

[3] Although claim 1 is not asserted in this litigation, all of the asserted claims depend from claim 1. The asserted claims therefore include each limitation of independent claim 1.

1. "a coating that, upon ingestion of said unit dosage form by said patient, prevents the release of essentially any NSAID from said dosage form unless the pH of the surrounding medium is 3.5 or higher" (Claims 5, 15, and 52–54)

AstraZeneca's and Pozen's Proposed Construction	Defendants' Proposed Construction
No construction is needed. This phrase should be given its plain and ordinary meaning.	A coating that, upon ingestion of said unit dosage form by said patient, ***controls the release of NSAID by time or pH*** and thereby prevents the release of essentially any NSAID from said dosage form unless the pH of the surrounding medium is 3.5 or higher

AstraZeneca and Pozen submit that this phrase should be given its customary and ordinary meaning. In other words, this phrase means exactly what it states—that the coating prevents release of the NSAID unless the pH of the surrounding medium is 3.5 or higher, and thus the coating controls release by pH only. In contrast, Defendants' construction ignores the plain language of the claim and broadens the claim to include coatings that control release by either time or pH.

Intrinsic Evidence: The plain language of claim 1 requires that the coating controls the release of the NSAID by pH rather than by time. Each of the independent claims in the '907 patent covers one of the two alternative embodiments of the invention—either a time-dependent or a pH-dependent embodiment. Claim 1 covers the pH-dependent embodiment, while independent claim 37 covers the time-dependent embodiment. Claim 1 states that the coating prevents the release of the NSAID "***unless the pH of the surrounding medium is 3.5 or higher***." Thus, the ***only*** claimed form of control for NSAID release in claim 1 is by pH; that is, the NSAID cannot be released "unless" the pH is 3.5 or higher. There is absolutely no claim language directed to controlling the release of the NSAID by time. By contrast, claim 37 requires a coating "that dissolves ***at a rate*** such that said NSAID is not released until said gastric

pH is at 3.5 or higher," indicating that the NSAID release in claim 37 depends on time. Had the patentee contemplated claiming time-controlled NSAID release in claim 1, the patentee could have expressly included similar language to that in claim 37. However, the patentee chose to draft claim 1 by omitting language specifying a time-dependent release of the NSAID. As the Federal Circuit has explained, "a construction that flies in the face of the express language of the claim is not preferred." *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1324 (Fed. Cir. 2001) (rejecting proposed construction of claim language relating to communications established by a host processor as also including communications established by the user); *see also Phillips*, 415 F.3d at 1312 ("It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude."). Consequently, the asserted claims—by their own terms—cannot be construed as encompassing control of NSAID release by ***either*** time ***or*** pH as the Defendants propose.

The specification and the prosecution history confirm that this claim term should be given its plain and ordinary meaning, and that no further construction is necessary. Mirroring claims 1 and 37, the specification of the '907 patent discloses two ***alternative*** embodiments relating to NSAID release. The specification makes clear that these two embodiments are different, and that claim 1 is drawn to ***only one*** of these two alternatives. The specification describes coatings that dissolve based on the pH of the surrounding medium, as well as ***different*** coatings that control the release of NSAID based on time:

> In the most preferred form, coordinated delivery is accomplished by having the inner core surrounded by a polymeric barrier coating ***that does not dissolve unless the surrounding medium is at a pH of at least 3.5***, preferably at least 4 and more preferably, at least 5. ***Alternatively, a barrier coating may be employed which controls the release of NSAID by time***, as opposed to pH, with the rate adjusted so that NSAID is not released until after the pH of the gastrointestinal tract has risen to at least 3.5, preferably at least 4,

> and more preferably at least 5. Thus, a time-release formulation may be used to prevent the gastric presence of NSAID until mucosal tissue is no longer exposed to the damage enhancing effect of very low pH.

Andersen Decl., Ex. 1, col.4 ll.5–17 (emphases added); *see also id*. at col.4 ll.32–38.

Claim 1 incorporates the ***exact*** language from the specification regarding pH-dependent release, but notably does ***not*** include the language about the ***alternative*** coatings that control the release by time, which are specifically claimed in unasserted claim 37. Consequently, although the specification describes two different types of NSAID coatings, claim 1 covers only pH-dependent coatings. That claim 1 does not cover both of the NSAID coating embodiments disclosed in the specification is of no moment. The Federal Circuit has explained that "a claim need not cover all embodiments . . . . A patentee may draft different claims to cover different embodiments." *Intamin Ltd. v. Magnetar Techs., Corp.*, 483 F.3d 1328, 1337–38 (Fed. Cir. 2007).

The prosecution history also supports AstraZeneca's construction. Specifically, the prosecution history reveals that claim 1 was limited by amendment to include a pH-controlled NSAID coating. As originally filed, claim 1 did not require an NSAID coating at all. *See* Andersen Decl., Ex. 2, at 30. In the final amendment before the Examiner allowed the claims, however, the patentee added the now-disputed phrase to claim 1. This amendment introduced the limitation that the pharmaceutical composition include "***a coating that . . . prevents the release of essentially any NSAID from said dosage form unless the pH of the surrounding medium is 3.5 or higher***." Andersen Decl., Ex. 3, at 2 (emphasis added). Consequently, the amendment limited the scope of claim 1 to a pharmaceutical composition comprising the pH-controlled NSAID coating embodiment described in the specification. Because the patentee deliberately chose ***not*** to claim a time-controlled NSAID coating in claim 1, this claim should

not be construed to include that embodiment. *See Sinorgchem Co. v. Int'l Trade Comm'n*, 511 F.3d 1132, 1138–39 (Fed. Cir. 2007) ("Where, as here, multiple embodiments are disclosed, we have previously interpreted claims to exclude embodiments where those embodiments are inconsistent with unambiguous language in the patent's specification or prosecution history.").

In summary, Defendants' proposed construction is contrary to the plain meaning of the claim language. It also ignores the language of the specification, and improperly expands the definition of the NSAID coating to include an embodiment that was specifically excluded from the claim during prosecution. The phrase should be construed exactly as it is written—as a coating that, upon ingestion of said unit dosage form by said patient, prevents the release of essentially any NSAID from said dosage form unless the pH of the surrounding medium is 3.5 or higher.

2. "enteric coating" (Claims 5, 15, and 52–54)

AstraZeneca and Pozen's Proposed Construction	Defendants' Proposed Construction
A delayed release coating	A coating that controls the release of an active agent from a unit dosage form ***by pH***

AstraZeneca and Pozen submit that the term "enteric coating" should be construed as one of skill would understand it in view of the claims, the specification and prosecution history: a delayed-release coating. In contrast, Defendants' construction seeks to import a limitation into the claims by limiting the enteric coating to one that controls the release of an active ingredient from a unit dosage form "by pH." Because there is no legitimate basis to import this limitation into the claims, the Court should reject Defendants' proposed construction.

Intrinsic Evidence: Generally, the term "enteric" broadly refers to the location of the gastrointestinal tract that is after the stomach, *i.e.*, the intestine. *See, e.g.*, Andersen Decl., Ex. 1, col.1 l.64–col.2 l.2 ("[T]his class of drugs is enteric coated to avoid destruction by stomach

acid."); *id.* at col.9 ll.50–57 ("The function of the enteric coat is to delay the release of naproxen . . . . The coating does not dissolve in the harshly acidic pH of the unprotected stomach."). In other words, the term "enteric" would be understood by a person of ordinary skill in the art as a coating that delays dissolution of the coating and release of the drug, but does not limit the manner in which the drug release is delayed. Defendants' construction is inappropriately limiting, because, while pH is ***one way*** of controlling and delaying drug release, it is not the ***only way.***

The language of the claims establishes that "enteric coating" has its plain and ordinary meaning, and thus a broader meaning than a coating that controls release of an active ingredient only "by pH" as Defendants propose. The relevant portion of claim 1 states:

> at least a portion of said acid inhibitor is not surrounded by an ***enteric coating*** and, upon ingestion of said unit dosage form by said patient, is released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5.

This phrase not only requires that (1) at least some of the acid inhibitor is not enteric coated, but also further requires that (2) the non-enteric coated acid inhibitor releases irrespective of pH. If an enteric coating is a coating that dissolves based on pH alone, as Defendants contend, the language requiring that the acid inhibitor releases irrespective of pH would render the "enteric coating" limitation superfluous. Using Defendants' proposed construction, the claim would read:

> at least a portion of said acid inhibitor is ***not surrounded by a coating that controls the release of an active agent from a unit dosage form by pH*** and, upon ingestion of said unit dosage form by said patient, ***is released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5***.

An acid inhibitor lacking a coating that prevents release by pH ***would by definition release irrespective of pH***, and in view of the limitation already requiring that the acid inhibitor be released regardless of pH, would be superfluous. *See Exxon Chem. Patents, Inc. v. Lubrizol*

Corp., 64 F.3d 1553, 1557 (Fed. Cir. 1995) (explaining that claims may not be construed in a manner that renders a claim term meaningless or superfluous).

The specification likewise demonstrates that an "enteric coating" is something more than just a coating that releases by pH. In the background section of the specification, for example, the patentee refers to "[t]he addition of a ***pH sensitive enteric coating*** to an NSAID." Andersen Decl., Ex. 1, col.2 ll.2–13 (emphasis added). If enteric coatings were, by definition, pH-sensitive, it would be meaningless for the patentee to specify that one particular enteric coating is "pH sensitive." *See Phillips*, 415 F.3d at 1312–13 (explaining that the term "steel baffles" in the claims "strongly implies" that the term "baffles" is not inherently limited to being made of steel). And, consistent with AstraZeneca and Pozen's proposed construction, the specification also repeatedly describes enteric coatings as coatings used to delay the release of drug. *See* Andersen Decl., Ex. 1, col.9 ll.50–52; col.10 ll.57–58; col.11 l.67–col.12 l.1 ("The function of the enteric coat is to delay the release of naproxen."); *id*. at col.16 ll.32–33 ("The release of naproxen sodium is delayed by enteric coating.").

Finally, the prosecution history also confirms that the claim language "enteric coating" is not limited to coatings that control release by pH. During prosecution, the patentee described enteric coatings as coatings that delay release of a drug, and relied on this feature to distinguish the claims over the prior art. The Examiner rejected the pending claims as anticipated by a patent allegedly disclosing an enteric-coated acid inhibitor (PPI).[4] At the time, claim 1 recited "an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5," and did not indicate that at least a portion of the acid inhibitor is not surrounded by an enteric coating. *See* Andersen Decl., Ex. 4, at 3. To overcome the rejection, the patentee

[4] Depui (U.S. Patent No. 6,613,354).

amended pending claim 1 to exclude an enteric coating on at least a portion of the acid inhibitor (PPI).[5] Applicant emphasized that in the prior art, the acid inhibitors were enteric coated, and drug release "would be ***delayed*** whereas acid inhibitor release from Applicant's compositions is immediate." *See* Andersen Decl., Ex. 3, at 2; 11–12 (emphasis added). The Examiner then allowed the claims. Thus, the Applicant broadly categorized the enteric-release coatings of the prior art as delayed release coatings, and the Examiner accepted this definition.

Extrinsic Evidence: A skilled person in the art at the time of the invention would not understand the term "enteric coating" to be limited to a pH-dependent coating. *See* Declaration of Dr. Robert O. Williams III, Ph.D. ¶¶ 33–37 ("Williams Decl."). Rather, a skilled person would understand "enteric coating" to mean a delayed release coating, typically used to delay release of a drug until it reaches the intestines. *Id*. Indeed, around the time of the invention, the Food and Drug Administration ("FDA") characterized enteric coatings as "[i]ntended to delay the release of the drug (or drugs) until the dosage form has passed through the stomach" and "delayed release dosage forms." *Id*. ¶¶ 34–35.[6]

As Dr. Williams explains, one skilled in the art would know of a variety of mechanisms by which enteric coatings can delay release of a drug until it reaches the intestines. *See* Williams Decl. ¶ 36. Some enteric coatings delay release by using pH-dependent polymers that only dissolve above a pre-determined pH threshold. *See id.* Other types of enteric coatings are formulated to release after a pre-determined amount of time. *See id*. More recently, enteric

[5] The Patentee amended the claims to include the phrase of issued claim 1 stating that, "at least a portion of said acid inhibitor is not surrounded by an enteric coating and, upon ingestion of said unit dosage form by said patient, is released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5." Andersen Decl., Ex.3, at 2.

[6] The FDA document relied upon by Dr. Williams is dated September 1997, and was therefore available at the time of the invention.

coatings have been designed that release in the intestines using bacteria that break down the coating to release the drug. *See id.*

In sum, Defendants proposed construction attempts to improperly limit the definition of "enteric coating" to just one type of enteric coating—a pH-sensitive coating. But the intrinsic record offers no legitimate basis to depart from the plain and ordinary meaning that "enteric coating" would have to those of skill in the art. *See Thorner v. Sony Computer Entertainment Am. LLC*, 669 F.3d 1362 (Fed. Cir. 2012) (The "only two exceptions" to the plain and ordinary meaning of claim term are when the patentee acts as its own lexicographer, or when the patentee disavows the full scope of the claim term in the specification or during prosecution). Indeed, Defendants' proposed construction runs contrary to the description in the specification and statements in the prosecution history. Consequently, "enteric coating" should not be limited to just one type of enteric coating, but should be given its full meaning—a coating that delays release of a drug.

3. "at least a portion of said acid inhibitor is not surrounded by an enteric coating and, upon ingestion of said unit dosage form by said patient, is released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5" (Claims 5, 15, and 52–54)

AstraZeneca and Pozen's Proposed Construction	Defendants' Proposed Construction
This phrase should be given its plain and ordinary meaning. The plain and ordinary meaning is: At least a portion of said proton pump inhibitor is immediately released	No construction is needed. This phrase should be given its plain and ordinary meaning.

AstraZeneca and Pozen agree with Defendants that this phrase should be given its plain and ordinary meaning. Defendants, however, have not articulated how the plain and ordinary meaning deviates from AstraZeneca and Pozen's proposed construction in light of the intrinsic evidence, *i.e.*, that at least a portion of the acid inhibitor is immediately released.

Intrinsic Evidence: The claims themselves require that at least a portion of the acid inhibitor is immediately released. Claim 1 provides that at least a portion of the acid inhibitor is not enteric coated and releases upon ingestion, irrespective of pH. The absence of an enteric coating (a delayed-release coating) results in the acid inhibitor releasing immediately, regardless of the pH the stomach (which may be well below 3.5).

The specification confirms this plain and ordinary meaning. Indeed, the specification repeatedly explains that "[t]he outermost layer [of the dosage form] contains an 'acid inhibitor' in an effective amount which is released from the dosage form ***immediately*** after administration to the patient." Andersen Decl., Ex. 1, col.8 ll.47–49; col.9 ll.60–62; col.10 l.66–col.11 l.1; col.12 ll.9–11 (emphasis added). Furthermore, every single example of a dosage form in the specification (Examples 1–7) characterizes the acid inhibitor as "immediate release."[7]

Finally, the prosecution history compels a construction of immediate release of at least a portion of the acid inhibitor. During prosecution, the patentee added the disputed phrase to claim 1. In the remarks accompanying the amendment, the patentee emphasized that "release from Applicant's [claimed] compositions is ***immediate***." Andersen Decl., Ex. 3, at 2; 11–12 (emphasis added). The claims should not now be construed differently. *See Gillespie v. Dywidag Sys. Int'l, USA*, 501 F.3d 1285, 1291 (Fed. Cir. 2007) (explaining that patentee should be held to "what he declare[d] during the prosecution of his patent."); *Liquid Dynamics Corp. v. Vaughn Co.*, 355 F.3d 1361, 1367–68 (Fed. Cir. 2004) (explaining that patentee's statements made during prosecution can serve to clarify the scope of the term at issue).

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[7] For instance, the dosage form of Example 5 is called "*Enteric Coated Naproxen Sodium Core and Pantoprazole* ***Immediate Release*** *in Film Coat*." Andersen Decl., Ex. 1, col.12 ll.62 (emphasis added). Example 6 is called "*Enteric Coated Naproxen Sodium Core and Omeprazole* ***Immediate Release*** *in Film Coat*." *Id*. at col.14 ll.41–42 (emphasis added). Example 7 is called "*Naproxen Sodium Delayed Release Omeprazole* ***Immediate Release*** *Capsule*." *Id*. at col.16 ll.21–22 (emphasis added).

Extrinsic Evidence: AstraZeneca's construction of the claim term is also consistent with the ordinary and customary meaning one of ordinary skill in the art would attribute thereto. One of ordinary skill would understand that an acid inhibitor lacking an enteric coating (*i.e.*, lacking a delayed release coating) will immediately release into stomach upon ingestion irrespective of pH. *See* Williams Decl. ¶ 39. As Dr. Williams explains, "immediately release" means that the dosage form "[a]llows the drug to dissolve in the gastrointestinal contents, with no intention of delaying or prolonging the dissolution or absorption of the drug." *Id.* ¶ 40. Dr. Williams bases his understanding of "immediate release" on FDA's definition of the term.[8] *Id.*

B. '872 Patent Claim Language In Dispute

The '872 patent claims the magnesium salts of the (–)-enantiomer of omeprazole exhibiting high or very high optical purities of "at least about": 94% (claim 1), 98.4% (claim 4), 99.8% (claim 7), and 99.9% (claim 10), measured by enantiomeric excess ("e.e."). Andersen Decl., Ex. 5.[9] Claims 5, 8, and 11 are parallel to claims 4, 7, and 10, only the "about" language is removed. *Id.* Claims 3, 6, and 9 limit the independent claims to those containing esomeprazole magnesium compounds "in crystalline form." *Id.*

Esomeprazole is the S-isomer, or (–)-enantiomer, of omeprazole, the first used PPI (also discovered by AstraZeneca). Enantiomers are mirror images of each other, much like our hands are mirror images of each other. *See* Declaration of Dr. Stephen G. Davies on Claim Construction ¶¶ 21–28 ("Davies Decl."). Omeprazole is a "racemic mixture," or "racemate," which means that it consists of a 50:50 mixture of two compounds called "enantiomers." *Id.*

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[8] The FDA explains that an immediate release dosage form "[a]llows the drug to dissolve in the gastrointestinal contents, with no intention of delaying or prolonging the dissolution or absorption of the drug."

[9] The parties' Joint Claim Construction Submission is submitted with this brief. *See* Andersen Decl., Ex. 6.

Although successful in treating a number of gastric-acid-related diseases, omeprazole exhibited substantial interindividual variation in therapeutic efficacy. Scientists at AstraZeneca discovered that alkaline salts of esomeprazole provided improved efficacy and decreased interindividual variation; the esomeprazole magnesium in Nexium® and Vimovo® is an alkaline salt of esomeprazole.

1. "In crystalline form" (Claims 3, 6, and 9)

AstraZeneca's Construction	Defendants' Construction
at least some of the magnesium salt of esomeprazole present is in a solid with a repeating pattern of atoms or molecules of the constituent chemical species	a solid in which the constituent molecules are arranged in an orderly, repeating pattern or lattice, in all three spatial dimensions

The Court previously construed this term in *Dr. Reddy's*, 2010 WL 1981790 at *3, to mean ***at least some of the magnesium salt of esomeprazole present is in a solid with a repeating pattern of atoms or molecules of the constituent chemical species***. In doing so, the Court rejected the same construction raised by Defendants here. The Court's previous constructions were correct. AstraZeneca respectfully requests that the Court adopt the same constructions here, for the reasons set forth in *Dr. Reddy's*.

C. '504 Patent Claim Language In Dispute

The '504 patent (Andersen Decl., Ex. 7) claims pharmaceutical formulations (and treatment methods) comprising solid, chemically pure alkaline salts of the (–)-enantiomer of omeprazole and a pharmaceutically acceptable carrier. This claim is further limited to "optically pure" alkaline salts of (–)-omeprazole (claim 2); specific alkaline salts, such as magnesium or sodium (claims 3 and 5); and salts in a "substantially crystalline form" (claim 4). Claims 6 and 10 are directed to methods of using the claimed formulation.

1. "(–)-enantiomer of 5-methoxy-2[[(4-methoxy-3,5-dimethyl-2-pyridinyl)met-hyl]sulfinyl]-1H-benzimidazole" (Claims 1–6 and 10) and as modified by "optically pure" (Claim 2)

AstraZeneca's Construction	Defendants' Construction
(–)-omeprazole of high optical purity, also referred to as (S)-omeprazole, the (S)-enantiomer of omeprazole, wherein "high optical purity" means at least 94% enantiomeric excess (e.e.) – and when modified by "optically pure" – in at least 98% enantiomeric excess	the chemical name for esomeprazole or S-omeprazole – and when modified by "optically pure" – essentially free of R-omeprazole

The Court previously construed "(–)-enantiomer of 5-methoxy-2[[(4-methoxy-3,5-dimethyl-2-pyridinyl)met-hyl]sulfinyl]-1H-benzimidazole" and "optically pure" in *Dr. Reddy's*, 2010 WL 1981790 at *6–8, to mean ***(–)-omeprazole of high optical purity, also referred to as (S)-omeprazole, the (S)-enantiomer of omeprazole***, wherein "high optical purity" means ***at least 94% enantiomeric excess (e.e.)***; and, when modified by "optically pure," ***in at least 98% enantiomeric excess***.[10] In doing so, the Court rejected arguments now advanced by Defendants. The Court's previous constructions were correct. AstraZeneca respectfully requests that the Court adopt those constructions here, for the reasons set forth in *Dr. Reddy's*.

2. "In substantially crystalline form" (Claim 4)

AstraZeneca's Construction	Defendants' Construction
sufficient crystallinity present to permit further optical purification of the enantiomer if required	solid esomeprazole in which almost all of the constituent molecules are arranged in an orderly, repeating pattern, or lattice, in all three spatial dimensions.

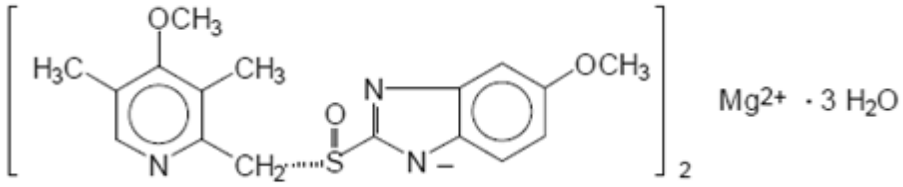
The Court previously construed this term in *Dr. Reddy's*, 2010 WL 1981790 at *8, to

[10] The ratio of enantiomers in a mixture is sometimes generally referred to as its "optical purity." "Enantiomeric excess" (e.e.), is one way to quantify optical purity, and reflects the difference between the percentages of the major and minor enantiomers in a mixture. For example, 94% enantiomer excess (–)-omeprazole means that the ratio of major to minor enantiomers in the mixture is 97:3 (an excess of 94% of (–) relative to (+)). *See* Davies Decl. ¶ 28.

mean ***sufficient crystallinity present to permit further optical purification of the enantiomer if required***. In doing so, the Court rejected the same arguments again raised by Defendants. The Court's previous constructions were correct. AstraZeneca respectfully requests that the Court adopt the same constructions here, for the reasons set forth in *Dr. Reddy's*.

D. '085, '070, and '466 Patent Claim Language In Dispute

As stated above, Vimovo® is a combination product containing naproxen and the trihydrate form of esomeprazole magnesium. The structural formula of esomeprazole magnesium trihydrate is:



The '085 and '070 patents protect the invention of esomeprazole magnesium trihydrate; while the '466 patent protects the invention of the combination of esomeprazole magnesium trihydrate and a second active ingredient, selected from a group that includes NSAIDs. The three patents have the same inventors and specification, but different claims. The '085 patent issued first, and is limited to a specific form of "the magnesium salt of S-omeprazole trihydrate" characterized by certain x-ray diffraction "d-values." Andersen Decl., Ex. 8, col.10 ll.15–34. The '070 patent later issued without any restrictions on the characteristics of the claimed esomeprazole magnesium trihydrate. *See* Andersen Decl., Ex. 9, col.10 l.52. The '466 patent claims pharmaceutical compositions and methods of treatment comprising the esomeprazole magnesium trihydrate (as broadly claimed in the '070 patent) and a second active ingredient. *See* Andersen Decl., Ex. 10, col.10 ll.50–60. Dr. Stephen Byrn, a leading expert on solid state chemistry, provides a declaration explaining a skilled person's understanding.

1. "magnesium salt of S-omeprazole trihydrate" ('085 Patent, Claims 1–4 and 12; '070 Patent, Claims 1–4; and '466 Patent, Claims 1–5, 7–14, and 16)

AstraZeneca's Construction	Defendants' Construction
"magnesium salt" means "a compound formed between positively-charged Magnesium (Mg) cations and negatively-charged esomeprazole anions," and "S-omeprazole trihydrate" means (S)-omeprazole having a structure that has a theoretical ratio of three molecules of bound water per molecule of $((S)\text{-omeprazole})_2$ magnesium, but which does not necessarily contain exactly three molecules of water, whose structure may be determined by analytical methods identified in the patent and known to those of ordinary skill. In '085 patent, the structure is determined by examining XRD.	A trihydrate of a magnesium salt of S-omeprazole containing three molecules of water per molecule of magnesium salt of S-omeprazole in a unit cell of the crystal lattice that is substantially free from magnesium salts of R-omeprazole and other prior art forms of magnesium salts of S-omeprazole including S-omeprazole dihydrate and amorphous forms

The term "magnesium salt of S-omeprazole trihydrate" appears in all asserted claims of the '085, '070, and '466 patents. AstraZeneca's construction is supported by both the intrinsic and extrinsic evidence. Defendants' construction, on the other hand, incorrectly seeks to import three limitations (crystallinity, purity in terms of the magnesium salt of the R-enantiomer, and purity in terms of other hydrate forms) in a way not contemplated by the patent.

Intrinsic Evidence: The claim language "the magnesium salt of esomeprazole trihydrate" does not further limit the form, purity, or concentration of the claimed compound. Claim 1 of the '070 patent is a simple compound claim; other claims address preferred embodiments and processes and pharmaceutical compositions, *see* Andersen Decl., Ex. 8, col.10 l.15–col.12 l.5. The broad scope of the term "the magnesium salt of S-omeprazole trihydrate" is apparent by contrasting claim 1 of the '070 patent to the other claims. Claim 1 of the '070 patent simply reads "The magnesium salt of S-omeprazole trihydrate." By contrast, claim 1 of the '085 patent addresses a preferred embodiment that "is characterized by the following major peaks in its X-ray diffractogram: [d-value / Å and intensity peak list]." Andersen Decl., Ex. 8, col.10

ll.15–33. Claim 2 of the '085 patent further limits claim 1 to the compound "in a highly crystalline form." *Id.* at col.10 ll.34–36. The additional crystallinity limitation in Claim 2 shows that "the magnesium salt of S-omeprazole trihydrate" does not require any particular level of crystallinity. The claims therefore indicate that the term "the magnesium salt of esomeprazole trihydrate" broadly covers the compound and is not further limited to a particular form, purity, or concentration.

The specification also makes clear that the term "magnesium salt of S-omeprazole trihydrate" is not limited to any particular form, degree of crystallinity, or amount. The shared specification of these patents states only that the invention relates to a novel form of the (–)-enantiomer of omeprazole—a trihydrate form. *See, e.g.*, Andersen Decl., Ex. 8, col.1 ll.7–16. The specification also states that the magnesium salt of S-omeprazole occurs in a number of structurally different forms, showing that the phrase "the magnesium salt of S-omeprazole trihydrate" includes all manifestations of that trihydrate form. *Id.* at col.2 ll.14–15. As the trihydrate in ***any amount*** was novel at the time of the invention, the term does not require a particular concentration or purity. Further, the magnesium salt of esomeprazole trihydrate can be characterized/identified using different analytical techniques, including FT-IR, which does not require crystallinity for detection and characterization. *See id.* at col.2 ll.38–41, 58–59; col.3 ll.50–56. Thus, the specification does not require the "magnesium salt of S-omeprazole trihydrate" to exhibit any minimum level of crystallinity.

While the shared specification of the three patents does describe characteristics found in some examples of the compound, these characteristics do not limit the scope of the claimed invention. *See* Andersen Decl., Ex. 8, col.2 ll.21–28, 39–42, 47–50, 58–59. The specification expressly states that examples provided ***are not*** intended to limit the scope of the invention. *See*

Andersen Decl., Ex. 8, col.5 ll.4–5; *see also SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1352 (Fed. Cir. 2005).

The prosecution history also strongly supports AstraZeneca's construction, and indicates the "magnesium salt of esomeprazole trihydrate" is not further limited in specific form, purity, or concentration. The Langkilde Declaration, submitted during prosecution of the '085 patent, states that "at the time the claimed invention was made, there was no suggestion that the magnesium salt of S-omeprazole existed in a trihydrate form. It was indeed surprising, therefore, to obtain the claimed compound." *See* Andersen Decl., Ex. 11. Thus, at the time of the invention, any amount, purity, or concentration of the compound was novel and inventive. Furthermore, claim 1 of U.S. Application No. 09/077,719 (the "'719 application," the parent application to the application that matured into the '085 patent) did not specify or limit the claimed esomeprazole magnesium trihydrate as to form, purity, or concentration. *See* Andersen Decl., Ex. 12, at 20. Claim 1 of the '719 application is the same as claim 1 of the issued '070 patent, while the additional limitations of claim 1 of the '085 patent were part of dependent claim 3 of the '719 application. *See id.* Further, the Examiner acknowledged the instant trihydrate as including, but not limited to, the crystalline form. *See* Andersen Decl., Exs. 13, 14.

Also, the PTO acknowledged that "the magnesium salt of S-omeprazole trihydrate" is not limited to a particular form having a certain XRD pattern. Claims 1 and 2 of the '070 patent were rejected during prosecution for statutory double patenting, as being the same as '085 patent Claims 1 and 2. *See* Andersen Decl., Ex. 15. AstraZeneca appealed this final rejection, explaining that the '070 claims are different and broader in scope than those in the '085 patent, and that the prosecution history of both patents supports and is consistent with this position.

See Andersen Decl., Ex. 16. In response to AstraZeneca's appeal, the Examiner withdrew the final rejection. *See* Andersen Decl., Ex. 17.

Extrinsic Evidence: A skilled person understands that the claim language the "magnesium salt of esomeprazole trihydrate" does not require, specify, or limit as to extent of crystallinity, purity, or concentration. Declaration of Dr. Stephen R. Byrn on Claim Construction ¶¶ 16–23 ("Byrn Decl."). The skilled person understands that a "trihydrate" describes a compound, in theory, having three bound molecules of water per every molecule of the magnesium salt of S-omeprazole (theoretical or stoichiometric ratio). *Id*. ¶ 17 ("[T]he skilled person would also understand the term hydrate, as used in the term trihydrate, as meaning that the associated water is bound to the molecules of the compound."). "[A] hydrate need not be crystalline to be considered a hydrate, although it must have some structure that can bind water in a regular way. The term hydrate differentiates a compound from other substances in which the water present is loosely associated or only present on the surface." *Id.*

2. "highly crystalline form" ('085 Patent, Claims 2, 4, 12; '466 Patent, Claims 4 and 12)

AstraZeneca's Construction	Defendants' Construction
a form having a repeating pattern of atoms or molecules in an order that can be detected by techniques known in the art, that is more ordered than previously known and disclosed forms	having a crystallinity higher than any other form of magnesium salt of S-omeprazole disclosed in the prior art

The term "highly crystalline form" appears in claims 2, 4, and 12 of the '085 patent; and claims 4 and 12 of the '466 patent. The term "crystalline" is understood by skilled persons as having its plain meaning, namely a substance in which the atoms or molecules are arranged in an ordered, repeating pattern. Byrn Decl. ¶¶ 24–25. AstraZeneca submits that intrinsic and extrinsic evidence compel its construction of "highly crystalline form."

Intrinsic Evidence: The specification indicates that the "highly crystalline" compounds of the invention are "characterized by . . . having a higher crystallinity than any other form of magnesium salt of S-omeprazole disclosed in the prior art." Andersen Decl., Ex. 8, col.2 ll.47–50. Thus, "highly" crystalline is a comparative phrase that indicates a more crystalline structure than that of previously known and disclosed forms. *See also* Andersen Decl., Ex. 6.

Extrinsic Evidence: A person skilled in the art would understand the term "crystalline" as meaning a substance in which the atoms or molecules are arranged in an ordered, repeating pattern. *See* Andersen Decl., Exs. 18–19. Furthermore, a person of ordinary skill in the art would be aware of a number of different techniques to determine the degree of crystallinity of a structure, including, but not limited to: visual inspection using microscopy; polarizing light microscopy; scanning electron microscopy; Raman spectroscopy; density measurement; Differential Scanning Calorimetry ("DSC"); modulated temperature DSC; StepScan DSC; isothermal microcalorimetry ("IMC"); solution calorimetry ("SC"); thermal techniques; Nuclear Magnetic Resonance ("NMR"); Gravimetric Moisture Sorption ("GMS"); IR spectroscopy; near and mid-IR spectroscopy; Terahertz Pulsed Spectroscopy ("TPS"); and XRPD. *See, e.g., at least* Andersen Decl., Exs. 20–23. Finally, Dr. Byrn explains that crystallinity in the context of "highly crystalline" permits a mixture of crystalline and amorphous material—the phrase is comparative and merely indicates that the form is more ordered than those in the prior art. *See* Byrn Decl. ¶¶ 24–25.

IV. CONCLUSION

AstraZeneca and Pozen's claim constructions should be adopted for the reasons discussed above.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2012, a true and correct copy of PLAINTIFFS' OPENING *MARKMAN* SUBMISSION (with accompanying Andersen Declaration and Exhibits 1–23; Byrn Declaration and Exhibits A–G; Davies Declaration and Exhibits A–E; and Williams Declaration and Exhibits A–D) was caused to be served on the below listed counsel of record via the Court's Electronic Filing System and electronic mail:

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